



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Noninvasive Negative Pressure Ventilators

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Hyperlink to Related Coverage Policies

Diaphragmatic/Phrenic Nerve Stimulation Ventilator Weaning

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for noninvasive negative pressure ventilation devices is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for noninvasive negative pressure ventilation devices is available, the following conditions of coverage apply.

CIGNA covers noninvasive negative pressure ventilation with poncho wrap or body ventilator as medically necessary for stable or slowly progressing respiratory failure due to chest wall deformities, neuromuscular diseases, or central hypoventilation syndrome when ANY of the following criteria is met:

- significant daytime CO₂ retention (i.e., ≥ 50 mm Hg) with appropriately compensated pH
- mild daytime or nocturnal CO₂ retention (i.e., 45–50 mm Hg) with symptoms attributable to hypoventilation (e.g., morning headaches, restless sleep, nightmares, enuresis or daytime hypersomnolence)
- significant nocturnal hypoventilation or oxygen desaturation as noted on polysomnography

General Background

Conventional invasive mechanical ventilation (IMV) via tracheostomy or endotracheal intubation is a procedure used for the treatment of acute respiratory failure. The procedure is associated with a number of side effects which are linked to the tracheal tube or tracheostomy. Noninvasive ventilation refers to the ability to deliver ventilatory support without establishing an endotracheal airway. Intermittent negative extrathoracic pressure has been the traditional method of noninvasive ventilation. Negative pressure ventilation (NPV) has the advantage of leaving the upper airway free, allowing unimpeded speech. Noninvasive positive pressure ventilation (NIPPV) via a face or nasal mask has expanded the use of noninvasive ventilation in the treatment of chronic and acute ventilatory failure (Todisco, et al., 2004; Hillberg and Johnson, 1997; Corrado, et al., 1996).

Negative pressure ventilators support ventilation by applying intermittent subatmospheric pressure during inspiration, with expiration occurring as the pressure around the chest wall is allowed to return to atmospheric levels. All negative pressure devices have two major components: an applicator where negative subatmospheric pressure is generated at the surface of the body during inspiration and a pump which affects pressure changes. There are three modes for delivering NPV: intermittent negative pressure ventilation (INPV), negative/positive pressure, and continuous negative external pressure. INPV is the most commonly used mode. When operating in this mode, the respirator generates a set negative pressure around the body to initiate or assist inspiration. Expiration is passive, and expiratory pressure at the anterior thoracic surface is atmospheric (Ambrosino and Carrado, 2001).

Body ventilators apply pressure to the entire body below the neck. The iron lung was widely used in the 1950s to treat paralytic poliomyelitis during the poliovirus epidemic. The modern iron lung or tank ventilator is made of aluminum and plastic. Negative pressure is generated by bellows pumps incorporated into the structure of the ventilator or by separate rotary pumps. Lighter portable devices have evolved which are designed to apply pressure to the thorax and abdomen. These devices include the rigid cuirass devices and the jacket or poncho wrap. All body suits, like the pneumowrap or the poncho wrap applicators, are fitted over a rigid grid including the patient's rib cage and upper abdomen. The grid is anchored posteriorly with a backplate. The pneumowrap is attached to the negative pressure pump in a way similar to the cuirass. The cuirass or shell covers the anterior surface of the chest and upper abdomen. It is connected to the negative pressure pump through a tube and hose inlet on the center. Standard sizes are available with commercial devices, whereas it is possible to tailor custom-made shells to patients with thoracic deformities such as kyphoscoliosis. The portable devices are less efficient than the body ventilators, since they apply negative pressure to a smaller body surface area. The early versions of the negative pressure ventilator (i.e., iron lung) are too cumbersome for practical use by most patients at home. The smaller cuirass and body-wrap ventilators are more acceptable to most stable patients, although they still require considerable skill for successful operation (Benditt and McCool, 2010; Hill, 2004; Ambrosino and Carrado, 2001; Hillberg and Johnson, 1997).

It is recommended that noninvasive ventilation should not be used in patients who are unable to cooperate or who have impaired consciousness, problems with retained secretions, or hemodynamic instability. A major problem with the use of NPV is upper airway obstruction, occurring when the upper airway abductors fail to contract vigorously enough to oppose the intratracheal vacuum generated by the inspiratory cycle of the NPV. This is a severe problem during sleep in patients with prominent weakness of the muscles of the throat, tongue, jaw, and face. In most cases, the solution to this problem is to switch to positive-pressure ventilation. Although a patient's difficulty with retained secretions is sometimes a reason to use intubation instead of noninvasive ventilation, the use of manually or mechanically assisted coughing techniques can often provide adequate clearance of secretions and allow the use of noninvasive ventilatory support (Soo Hoo, 2010; Hillberg and Johnson, 1997).

Neuromuscular and chest disorders can lead to chronic ventilatory failure. This is seen, for example, in scoliosis, following a thoracoplasty, kyphosis, muscular dystrophies, poliomyelitis, and with motor neuron disease. Positive pressure techniques using nasal and face masks are usually the first choice, with NPV as an alternative. Careful patient selection is required, especially with progressive neuromuscular disorders such as Duchene muscular dystrophy and motor neuron disease. There is limited evidence studying the outcome of noninvasive ventilation in these conditions. Studies have shown an improved quality of life, physical activity and hemodynamics, improvement in blood gases, and slight improvement in other physiological measures such as maximal mouth pressures and vital capacity. Noninvasive ventilatory support may not increase survival if the underlying disorder is deteriorating, particularly if the bulbar muscles are involved (Shneerson and Simonds, 2002).

U.S. Food and Drug Administration (FDA)

Negative pressure devices are approved through the 510(k) premarket approval process as class II devices (FDA, 2010).

Literature Review

Although well-designed studies are lacking, the evidence in the published, peer-reviewed scientific literature suggests that of the use of the body ventilator or poncho wrap has benefit for a subset of patients with stable or slowly progressing respiratory failure due to chest wall deformities, neuromuscular diseases, or central hypoventilation syndrome (Corrado, et al., 2004; Todisco, et al., 2004; Corrado, et al., 2002; Baydur, et al., 2000).

Technology Assessments/Reviews

In an updated Cochrane review, Shah et al. (2008) assessed the effectiveness of continuous negative extrathoracic pressure ventilation (CNEP) and noninvasive continuous positive airway pressure ventilation (Ni-CPAP) in pediatric patients with acute hypoxemic respiratory failure due to noncardiogenic causes. The review found only one trial. The authors concluded that CNEP may be beneficial, but more trials are needed.

A consensus report by the National Association for Medical Direction of Respiratory Care (NAMDRRC) reviewed the clinical indications for NIPPV in chronic respiratory failure due to restrictive lung disease, COPD, and nocturnal hypoventilation. The report addressed the use of NPV to treat COPD. The authors reported that studies had conflicting results, casting doubt on the efficacy of intermittent negative pressure in treating patients with severe stable COPD (NAMDRRC, 1999).

Professional Societies/Organizations

A consensus statement from the American College of Chest Physicians (ACCP) on mechanical ventilation beyond the intensive care unit suggests, "negative pressure ventilation via chest shell or body wrap is not ideally adaptable to infants and young children due to unique upper airway anatomy, and young children may be fearful of a tank's confinement. Negative pressure technique may be ideal for some older children with neuromuscular disorders or transient respiratory failure if the technique makes a tracheostomy unnecessary." Positive pressure ventilation via tracheostomy is the usual method of assisted ventilation in infants and young children. The ACCP suggests NPV applied via a body tank, chest cuirass, or body wrap can effectively augment ventilation in long-term support; however, NPV is currently reserved for patients in whom positive pressure ventilation has failed, or as an alternate supplementary form of support for patients using other means of ventilatory assistance. Some of the conditions that meet criteria for noninvasive ventilation are neuromuscular disorders, chest wall deformity and central hypoventilation syndrome. There have been no updates to this consensus statement since 1998. The indications for noninvasive ventilation include the following (ACCP, 1998; Make, et al., 1998):

- The patient has a chronic, stable or slowly progressive respiratory failure as indicated by ANY of the following criteria:
 - significant daytime CO₂ retention (i.e., ≥ 50 mm Hg) with appropriately compensated pH
 - mild daytime or nocturnal CO₂ retention (i.e., 45–50 mm Hg) with symptoms attributable to hypoventilation (e.g., morning headaches, restless sleep, nightmares, enuresis or daytime hypersomnolence)
 - significant nocturnal hypoventilation or oxygen desaturation
- The following conditions have been met:
 - The patient has had optimal medical therapy for underlying respiratory disorders.
 - The patient is able to protect airway and adequately clear secretions.
 - The patient's reversible contributing factors have been treated (e.g., obstructive sleep apnea, hypothyroidism, congestive heart failure, severe electrolyte imbalance).

Summary

Negative pressure ventilation (NPV) has been primarily used in patients with chronic respiratory disorders. While there are limited clinical trials published regarding the efficacy of NPV in patients with chronic respiratory disorders, the American College of Chest Physicians (ACCP) supports NPV in a carefully selected subset of

individuals. This mode of noninvasive ventilation has become overshadowed with the evolution of noninvasive positive pressure ventilation (NIPPV) and is often the second choice if NIPPV is contraindicated or not tolerated.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
94662	Continuous negative pressure ventilation (CNP), initiation and management

HCPCS Codes	Description
E0457	Chest shell (cuirass)
E0459	Chest wrap
E0460	Negative pressure ventilator, portable or stationary
E1399 [†]	Durable medical equipment, miscellaneous

†Note: Covered when used to report noninvasive negative pressure ventilation body ventilator as medically necessary as indicated within the Coverage Policy.

ICD-9-CM Diagnosis Codes	Description
518.83	Chronic respiratory failure

***Current Procedural Terminology (CPT[®]) ©2010 American Medical Association: Chicago, IL.**

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Policy History

<u>Pre-Merger</u>	<u>Last Review</u>	<u>Policy</u>	<u>Title</u>
<u>Organizations</u>	<u>Date</u>	<u>Number</u>	
CIGNA HealthCare	12/15/2007	0433	Noninvasive Negative Pressure Ventilators

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